



PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO		Complete if Known			
		Application Number	10/030.392		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Filing Date	01/02/2002		
		First Named Inventor	M. Hanna et al.		
		Art Unit			
		Examiner Name	Unassigned		
Sheet	1	of	6	Attorney Docket Number	0112.00

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Figures Appear
		Number	Kind Code ² (if known)			
AV	AA	US-4,328,107		05/04/1982	Wright	
AV	AB	US-4,361,285		11/30/1982	Koppehele et al.	
AV	AC	US-4,582,731		04/15/1986	Smith	
AV	AD	US-4,702,799		10/27/1987	Tuot	
AV	AE	US-4,737,384		04/12/1988	Murthy et al.	
AV	AF	US-4,919,853		04/24/1990	Alvarez et al.	
AV	AG	US-4,923,720		05/08/1990	Lee et al.	
AV	AH	US-4,970,093		11/13/1990	Sievers et al.	
AV	AI	US-4,977,785		12/18/1990	Willoughby et al.	
AV	AJ	US-5,009,367		04/23/1991	Nielsen	
AV	AK	US-5,043,280		08/27/1991	Fischer et al.	
AV	AL	US-5,106,659		04/21/1992	Hastings et al.	
AV	AM	US-5,221,731		06/22/1993	Weymans et al.	
AV	AN	US-5,229,486		07/20/1993	Paul et al.	
AV	AO	US-5,437,798		08/01/1995	LaRoche et al.	
AV	AP	US-5,548,004		08/20/1996	Mandel et al.	
AV	AQ	US-5,554,382		09/10/1996	Castor	
AV	AR	US-5,639,441		06/17/1997	Sievers et al.	
AV	AS	US-5,707,634		01/13/1998	Schmitt	
AV	AT	US-5,708,039		01/13/1998	Daly et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³	Number ⁴ - Kind Code ⁵ (if known)			
AV	AX	DE	4041563	06/25/1992	Schwarz Pharma AG	
AV	AY	DE	1078283	03/24/1960	F. Aktiengesellschaft	
AV	AZ	EP	0322687	05/05/1993	W. Fischer	
AV	BA	EP	0542314	05/19/1993	P. Debenedetti	
AV	BB	JP	1-176437	07/12/1989	T. Tauchi	
AV	BC	JP	5-57166	03/09/1993	K. Kitagawa	
AV	BD	WO	90/11139	10/04/1990	K. Nielsen	
AV	BE	WO	90/03782	04/19/1990	W. Schmitt	
AV	CP	GB	2322326	08/26/1998	Bradford Particle	
AV	CO	WO	95/21688	08/17/1995	W. Eckhard et al.	

Examiner Signature

Date Considered

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		Filing Date	01/02/2002
		First Named Inventor	M. Hanna et al.
		Group Art Unit	
		Examiner Name	Unassigned
		Attorney Docket Number	0112.00
Sheet	3	of	6

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
UC	BF	DEBENEDETTI ET AL., "Application of Supercritical Fluids for the Production of Sustained Delivery Devices," J. Cont. Rel. No. 24, p. 27-44 (1993).
UC	BG	DIXON ET AL., "Polymeric Materials Formed by Precipitation with a Compressed Fluid Antisolvent," AIChE J., Vol. 39 (No. 1), p. 127-139 (1993).
EC	BH	TOM ET AL., "Applications of Supercritical Fluids in the Controlled Release of Drugs," ACS Symposium Series, Supercritical Fluid Engineering Science Fundamentals and Applications, Chpt. 19, p. 238-257 (1993).
UC	BI	LARSON ET AL., "Evaluation of Supercritical Fluid Extraction in the Pharmaceutical Industry," Biotech. Progress, Vol. 2 (No. 2), p. 73-82 (1986).
UC	BJ	Ullmans Encyclopedia of Industrial Chemistry, Vol. B2, Fifth Ed., title page, copyright page, and p. 7-21 and 7-22 (1988).
UC	BK	TOM ET AL., "Particle Formation with Supercritical Fluids - A Review," J. Aerosol Sci., 1st Ed. Vol. 22 (No. 5), p. 555-584 (1981).
UC	BL	DEBENEDETTI ET AL., "Rapid Expansion of Supercritical Solutions (RESS): Fundamentals and Applications," Fluid Phase Equilibria, Vol. 82, p. 311-321 (1993).
UC	BM	GALLAGHER ET AL., "Gas AntiSolvent Recrystallization: New Process to Recrystallize Compounds Insoluble in Supercritical Fluids," ACS Symp. Ser No. 406, p. 334-354 (1989).
UC	BN	LAHIERE ET AL., "Mass-Transfer Efficiencies of Column Contactors in Supercritical Extraction Service," Ind. Eng. Chem. Res. No. 26, p. 2086-2092 (1987).
UC	BO	STAHL ET AL., "Dense Gas Extraction on a Laboratory Scale: A Survey of Some Recent Results," Fluid Phase Equilibria, No. 10, p. 269-278 (1983).
UC	BP	DILL ET AL., "Denatured States of Proteins," Annu. Rev. Biochem, No. 60, p. 795-825 (1991).

Examiner Signature	<i>[Signature]</i>	Date Considered	2/9/04
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		Examiner Name	Unassigned
		Attorney Docket Number	0112.00
Sheet	4	of	6

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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
ue	BQ	O'CALLAGHAN ET AL., "Novel Method for Detection of (B)-Lactamases by Using a Chromogenic Cephalosporin Substrate." Antimicrobial Agents and Chemotherapy, Vol. 1 (No. 4), p. 283-288 (1972).	
ue	BR	JUNG ET AL., "Particle Design Using Supercritical Fluids: Literature and Patent Survey," J. of Supercritical Fluids, Vol. 20, p. 179-219 (2001).	
ue	BS	BLEICH ET AL., "Aerosol Solvent Extraction System - A New Microparticle Production Technique." International J. of Pharmaceutics, Vol. 97, p. 111-117 (1993).	
ue	BT	CHANG ET AL., "Separation of B-Carotene Mixtures Precipitated from Liquid Solvents with High-Pressure CO ₂ ," Biotechnol. Prog., No. 7, p. 275-278 (1991).	
ue	BU	GALLAGHER ET AL., "Gas Anti-Solvent Recrystallization of RDX: Formation of Ultra-fine Particles of a Difficult-to-Comminute Explosive." The J. of Supercritical Fluids, No. 5, p. 130-142 (1992).	
ue	BV	MATSON ET AL., "Production of Powders and Films by the Rapid Expansion of Supercritical Solutions." J. of Materials Science, No. 22, p. 1919-1928 (1987).	
ue	BW	MOHAMED ET AL., "Solids Formation After the Expansion of Supercritical Mixtures," Supercritical Fluid Science and Technology, Chapter 23, American Chemical Society, p. 355-378 (1989).	
ue	BX	BARJ ET AL., "Submicronic MgAl ₂ O ₄ Powder Synthesis in Supercritical Ethanol." J. of Materials Sci., No. 27, p. 2187-2192 (1992).	
ue	BY	CHHOR ET AL., "Synthesis of Submicron TiO ₂ Powders in Vapor, Liquid and Supercritical Phases, a Comparative Study," Materials Chemistry and Physics, Vol. 32, p. 249-254 (1992).	
ue	BZ	FRANCIS, "Ternary Systems of Liquid Carbon Dioxide," J. of Physical Chemistry, Vol. 58, p. 1099-1114 (1954).	
ue	CA	YEO ET AL., "Formation of Microparticulate Protein Powders Using a Supercritical Fluid Antisolvent," Biotechnology and Bioengineering, Vol. 41, p. 341-346 (1993).	

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
RU	CB	RANDOLPH ET AL., "Sub-Micrometer-Sized Biodegradable Particles of Poly (L-Lactic Acid) via the Gas Antisolvent Spray Precipitation Process." Biotechnol. Prog. Vol. 9, No. 4, p. 429-435 (1993).
RU	CC	DEBENEDETTI ET AL., "Supercritical Fluids : A New Medium for the Formation of Particles of Biomedical Interest." Proceed. Intern. Symp. Control Rel. Bioact. Mater., 20, p. 141-142 (1993).
RU	CD	DONSI ET AL., "Micronization by Means of Supercritical Fluids: Possibility of Application to Pharmaceutical Field." Pharm. ACTA HELV. 66, Nr. 5-6, p. 170-173 (1991).
RU	CE	CYGNAROWICZ ET AL., "Design and Control of a Process to Extract B-Carotene with Supercritical Carbon Dioxide." Biotechnol. Prog. Vol. 6, p. 82-91 (1990).
RU	CF	CHEN ET AL., "Supercritical Antisolvent Fractionation of Polyethylene Simulated with Multistage Algorithm and SAFTEquation of State: Staging Leads to High Selectivity Enhancements for Light Fractions." Ind. Eng. Chem. Res., Vol. 33, p. 306-310 (1994).
RU	CG	LOTH ET AL., "Properites and Dissolution of Drugs Micronized by Crystallization from Supercritical Gases." International J. of Pharmaceuticals, Vol. 32, p. 265-267 (1986).
RU	CH	BODMEIER ET AL., "Polymeric Microspheres Prepared by Spraying Into Compressed Carbon Dioxide," Pharmaceutical Research, Vol. 12, No. 8, p. 1211-1217 (1995).
RU	CI	TOM ET AL., "Formation of Bioerodible Polymeric Microspheres and Microparticles by Rapid Expansion of Supercritical Solutions," Biotechnol. Prog., Vol. 7, p. 403-411 (1991).
RU	CJ	SANCHEZ ET AL., "Development of Biodegradable Microspheres and Nanospheres for the Controlled Release of Cyclosporin A." International J. of Pharmaceutics, Vol. 99, p. 263-273 (1993).
RU	CK	JULIENNE ET AL., "Preparation of Poly (D, L-Lactide/Glycolide) Nanoparticles of Controlled Particle Size Distribution: Application of Experimental Designs," Drug Development and Industrial Pharmacy, Vol. 18, No. 10, p. 1063-1077 (1992).
RU	CL	PHILLIPS ET AL, "Rapid Expansion from Supercritical Solutions: Application to Pharmaceutical Processes," International J. of Pharmaceutics, Vol. 94, p. 1-10 (1993).

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS		
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CO	CM	CHANG ET AL., "Precipitation of Microsize Organic Particles from Supercritical Fluids," AIChE Journal, Vol. 35, No. 11, p. 1876-1882 (November 1989).
W	CN	MATSON ET AL., "Rapid Expansion of Supercritical Fluid Solutions: Solute Formation of Powders, Thin Films and Fibers." Ind. Eng. Chem Res., Vol. 26, p. 2298-2306 (1987).
W	CO	STENGERS ET AL., "Carbon Dioxide at its Critical State," Chemical & Engineering News, June 10, 1968.

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